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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Management of High-Need, High-Cost  
(HNHC) Patients: A Realist and Systematic Review

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Management of High-Need, High-Cost Patients: A Realist and Systematic Review*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before 30 days after date of publication.

ADDRESSES:

*E-mail submissions:* [epc@ahrq.hhs.gov](mailto:epc@ahrq.hhs.gov)

*Print submissions:*

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

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SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Management of High-Need, High-Cost Patients: A Realist and Systematic Review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Management of High-Need, High-Cost Patients: A Realist and Systematic Review*, including those that describe adverse events. The entire research protocol is available online at:

<https://effectivehealthcare.ahrq.gov/products/high-utilizers-health-care/protocol>

This is to notify the public that the EPC Program would find the following information on *Management of High-Need, High-Cost Patients: A Realist and Systematic Review* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.

- *For completed studies that do not have results on ClinicalTrials.gov, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.*
- *A list of ongoing studies that your organization has sponsored for this indication. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.*
- *Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.*

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

*The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.*

## **Key Questions (KQ)**

**KQ 1.** What criteria identify or can be used to predict that patients will be HNHC and why?

**KQ 1a.** How do criteria incorporate patient clinical characteristics?

**KQ 1b.** How do criteria incorporate patient health behaviors and sociodemographic characteristics (e.g., age, social determinants of health, insurance status and source of coverage, and access to the health care system)?

**KQ 1c.** How do criteria incorporate types, amount, duration, and patterns of persistent use of potentially preventable or modifiable health care use?

**KQ 1d.** Do criteria differ at the payer, health care system, or provider levels?

**KQ 1e.** How can observed or predicted potentially preventable or modifiable high use of health care be differentiated from necessary and appropriate use?

**KQ 2.** What are the mechanisms that lead to reductions in potentially preventable or modifiable health care use and result in improved health outcomes and cost savings in interventions serving HNHC patients?

**KQ 2a.** What are the important contexts, such as the characteristics of the HNHC patients, the broader health care delivery system, and the community, that impact whether mechanisms facilitate the desired outcomes?

**KQ 3.** Overall, what is the effectiveness and harms of interventions, included in answering KQ 2, in reducing potentially preventable or modifiable health care use and costs and improving health outcomes among HNHC patients?

**PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)**

PICOTS	Inclusion	Exclusion
Population	<p>KQs 1, 2, and 3: Noninstitutionalized adults, 18 years of age or older</p> <p>KQ 1: One or more years of potentially preventable or modifiable high health care cost and/or use</p> <p>KQs 2 and 3, two groups:</p> <p>a) HNHC patients with one or more years of potentially preventable or modifiable high health care cost and/or use;</p> <p>b) HNHC patients with one or more years of potentially preventable or modifiable high health care cost and/or use AND either 2 or more chronic physical health conditions, or a combination of 1 or more chronic physical health conditions and 1 or more behavioral health conditions</p>	<p>Patients receiving a high level of health care services that are considered appropriate for their condition OR high level of health care services are measured for less than 1 year OR end-of-life care</p>
Intervention	<p>KQ 1: Not relevant, interventions not necessary for inclusion</p> <p>KQs 2 and 3:</p> <p>Alternative delivery models (e.g., Accountable Care Organizations, coordinated care organizations, health homes, home-based primary care, behavioral health integration)</p> <p>System- or practice-level interventions (e.g., emergency department alerts, hotspotting)</p> <p>Patient supportive services (e.g., community health workers, social workers, patient navigators, care coordinators, case and care managers, intensive primary care support, medication management, health reliance specialists, self-management instruction, and peer-to-peer support)</p> <p>Social determinants of health-related interventions (e.g., transportation, health literacy, housing support, caregiver support)</p>	<p>KQs 2 and 3: Interventions for which the relevance for and impact on HNHC patients cannot be determined</p>
Comparator	<p>KQ 1: Comparison population or no comparator</p> <p>KQ 2: Any intervention, treatment as usual, or no comparator intervention</p> <p>KQ 3: Any intervention or treatment as usual</p>	<p>KQ 3: No comparator</p>
Outcomes	<p>KQ 1: Population characteristics described or predicted</p> <p>KQs 1, 2, and 3:</p> <p>Health care use: decreases in emergency department visits, emergency management services use, and hospitalizations; changes in primary care or specialist visits or other necessary and appropriate types of care (e.g., care manager visits, telephone followup) and use of support services</p> <p>Patient health behavior (e.g., treatment adherence, empowerment, knowledge, self-care)</p> <p>Patient health outcomes: all-cause mortality, disease and condition-specific outcomes, health indicators, quality of life</p> <p>Patient satisfaction with care</p> <p>Physicians' and health professionals' satisfaction with clinical practice</p> <p>Costs</p> <p>Patient and health professional harms such as increased barriers to necessary care, clinician time, and/or resource trade-offs of other</p>	<p>All other outcomes, including behavioral health outcomes</p>

PICOTS	Inclusion	Exclusion
	duties	
Time frame	Potentially preventable or modifiable high cost health care use measured for 1 year or more  KQ 3: Measurement of outcomes at 1 year or more after implementation of the intervention.	Shorter time periods
Settings	Health care and support services delivery settings, including outpatient, emergency department, the broader health care delivery environment, community characteristics related to social determinants of health  KQ 1: United States  KQs 2 and 3: patient-level interventions: very high human development index countries; Health system or payer-level interventions: United States	Institutional care settings, such as hospitals, skilled nursing, long-term care facilities, and prisons or jails
Study design	KQs 1 and 2: All study designs except reviews summarizing across original studies or interventions KQ 3: Randomized controlled trials, cluster randomized trials, cohort studies, case-control studies, quasi-experimental designs with a comparison group	KQ 3: All other designs
Language	Studies published in English	Studies published in languages other than English
Publication type	All publications that allow abstraction and interpretation of findings	KQ 3 only: Abstract-only publications

Dated: December 10, 2019.

Virginia Mackay-Smith

Associate Director

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